Remarks

Claims 1-12 and 14-56 are pending upon entry of the foregoing amendments.

Claims 1-10, 12, 14-30, and 34-56 are allowed.

Claims 11, 31, and 32 are rejected, but have now been amended so that they too should be deemed allowable for the same reasons described by the Examiner in the Office Action mailed March 19, 2008, for allowing claims 1-10, 12, 14-30, and 34-56.

Amendments to the Claims

Claim 11 has been amended to delete the term "derivatives."

Claims 31 and 32 have been amended to specify that the pharmaceutical agent is dispersed and encapsulated within the hydrophobic matrix material. That is, the drug is located *not* inside the pores of a microparticles (as taught in the DeLuca patent) but rather is part of the wall structure defining the pores and forming the microparticles. Support for these amendments can be found in the specification, for example, at page 12, lines 15-18.

Rejection under 35 U.S.C. § 112

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The rejection is respectfully traversed as moot.

The Examiner alleges that the phrase "derivatives" is vague and can encompass compounds not described in the specification. Applicants respectfully disagree and maintain—for the reasons detailed in their prior response—that the term "derivatives" would be sufficiently clear and definite to one of ordinary skill in the when the claim term is read in light of the specification. Patent law does not require that a patent specification explicitly list every single possible species that may come within a claimed genus in order for that patent claim to be

definite. Nevertheless, Claim 11 has been amended to eliminate the term "derivatives." The rejection therefore should be withdrawn as moot.

Rejection under 35 U.S.C. § 103

Claims 31 and 32 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,818,542 to DeLuca et al. (hereinafter "DeLuca") in view of U.S. Patent No. 6,395,300 to Straub et al. (hereinafter "Straub"). The rejection is respectfully traversed.

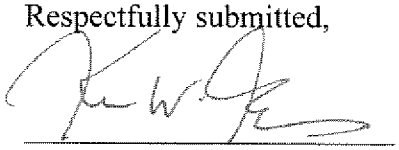
As Applicants explained in their prior response, DeLuca discloses a "pore incorporated" drug and fails to teach or suggest a microparticle drug formulation in which the pharmaceutical agent *is dispersed and encapsulated within the hydrophobic matrix material*, as now required by Applicants' claims 31 and 32. DeLuca also does not teach Applicants' claimed release profile or how to select the combination of the pharmaceutical agent, matrix material, geometric size, and average porosity to control release rate. Furthermore, Straub teaches away from Applicants' claims 31 and 32, which include a *hydrophobic* matrix material to *delay* drug release, because Straub teaches using a *hydrophilic* matrix material in order to *increase* drug release.

No *prima facie* case of obviousness has been established for claims 31 and 32 as amended.

Conclusions

Applicants submit that all of the claims are patentable over the prior art of record. Allowance of claims 1-12 and 14-56 is therefore respectfully solicited.

Respectfully submitted,



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Date: **April 23, 2008**

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